UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,613	11/14/2001	Pramod K. Srivastava	8449-183-999	9970

20583 7590 03/17/2006

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER
TIDWELL, JUDY LILLE

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/992,613	SRIVASTAVA, PRAMOD K.	
	Examiner	Art Unit	
	Judy Lille Tidwell, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,21,33-36,39-42,57,58,63,65,77-80,83-86,101,102,111-125 and 132* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/14/01, 12/26/02, 6/24/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 19,21,33-36,39-42,57,58,63,65,77-80,83-86,101,102,111-125 and 132.

Srivastava, P.K.

DETAILED ACTION

Application Status

Claims 19, 21, 33-36, 39-42, 57-58, 63, 65, 77-80, 83-86, 101-102, 111-125, 132 are currently pending and under consideration.

Claim Objections

Claim 132 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must be formed in the alternative to a preceding independent claim, not a dependent claim. See MPEP § 608.01(n).

Information Disclosure Statement

The Information Disclosure Statements filed on 11/14/2001, 12/26/2002, and 06/24/2005 have been considered. A signed copy of all 1449 forms are attached hereto.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19, 21, 33-36, 39-42, 63, 65, 77-80, 83-86, 115-118, 122-125 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42-48 of U.S. Patent No. 5,750,119 issued 05/12/1998 (08/315,892 filed 09/30/1994).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the active ingredient in the "immunogenic population" of the instant case in independent claims 19, 21, 63, and 65, "a composition" comprising a purified human stress protein-peptide complexes obtained from human tumor, more specifically a human gp96 noncovalently associated with a peptide, is also recited in claims 42-48 of U.S. Patent No. 5,750,119.

However, claims 1 and 23 of U.S. Patent No. 5,750,119 make it clear that the gp96-peptide complex is "immunogenic" *in vivo*, and not any other agent. Therefore, the preamble "immunogenic population" in the instant application is an intended use. In other words, there is no difference in the composition of both "immunogenic population" of the instant claims and "composition" in U.S. Patent No. 5,750,119. The difference is semantics.

Although the claims 42-48 of U.S. Patent No. 5,750,119 (08/315,892) do not say that the human gp96 protein-peptide complex was isolated from the specific tumor

tissues recited in the instant claims 115-118 and 122-125, the specification of U.S. Patent No. 5,750,119 contemplates that the isolated HSP protein-peptide complexes from tumors could be used in the treatment of a variety of tumor types (column 6, lines 41-65) which do recite the same types of tumor tissues in the instant claims. The instant claims and specification and the specification U.S. Patent No. 5,750,119 imply that the HSP protein-peptide complexes are isolated from the same tumor tissues that would be treated with said HSP protein-peptide complexes. Note the disclosure of the instant specification and the disclosure of U.S. Patent No. 5,750,119 should be the same because the instant specification is a continuation of 09/489,218 which is a continuation of 09/061,365 which is a divisional of 08/315,892.

Claims 57, 58, 101, 102, 113, 114, 121, 132 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42-48 of U.S. Patent No. 5,750,119 in view of Roitt et al. (Immunology, 3rd ed. Mosby, London, England, 1993).

The instant claims are drawn to an immunogenic population of the respective base claims plus adjuvants and/or cytokines, more specifically GM-CSF.

The claims of U.S. Patent No. 5,750,119 do not recite adjuvant. However, Roitt et al. (page 15.10) teach that adjuvants evoke stronger immune responses if they are mixed with bacterial components, such as an antigen, before the effective filing date of the application. Therefore, it would have been obvious to one of ordinary skill to make and use an immunogenic population of human gp96 protein-peptide complexes further comprising an adjuvant with a reasonable expectation of success.

The claims of U.S. Patent No. 5,750,119 do not recite cytokine or GM-CSF. However, Roitt et al. (pages 7.7, 17.12) teach that cytokines, and specifically GM-CSF, boost immune mechanisms and are used for tumor therapy before the effective filing date of the instant application. Therefore, it would have been obvious to one of ordinary skill to make and use an immunogenic population of human gp96 protein-peptide complexes further comprising a cytokine, GM-CSF, with a reasonable expectation of success.

Claims 111, 119 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42-48 of U.S. Patent No. 5,750,119 in view of Nakatsuwaga (U.S. Patent No. 4,434,788 issued 3/04/1984) and further in view of Sela et al. (U.S. Patent No. 4,093,607 issued 6/06/1978).

The instant claims are drawn to an immunogenic population of the respective base claims plus a chemotherapeutic agent or an antibiotic.

The claims of U.S. Patent No. 5,750,119 do not recite a chemotherapeutic agent or an antibiotic. However, Nakatsuwaga (column 12, claim 12) teaches that an anti-tumor agent include anti-metabolites, anti-tumor antibiotics, and alkylating agents which encompass chemotherapeutic and antibiotic compositions for cancer treatment before the effective filing date of the application. Sela et al. (column 1, lines 1-48) teach immunologic chemotherapeutic agents and anti-tumor antibiotics comprising antigen binding dimers covalently bound to drugs before the effective filing date of the application. Therefore it would have been obvious to one of ordinary skill to make and use a chemotherapeutic or antibiotic agent.

Claims 112, 120 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42-48 of U.S. Patent No. 5,750,119 in view of Kashdan (U.S. Patent No. 4,795,641 issued 01/03/1989) and further in view of Modlin (Surgery, Gynecology and Obstetrics, 1979, 149(5): 751-69).

The instant claims are drawn to an immunogenic population of the respective base claims plus a bioactive agent.

The claims of U.S. Patent No. 5,750,119 do not recite a bioactive agent.

The specification of the instant application does not define the boundary of "bioactive agent". Therefore, the office turned to the prior art to see what is encompassed by "bioactive agent". Kashdan (columns 15-16, claims 12-13) teaches that bioactive agents include a broad category of any type of agent that is bioactive before the effective filing date of the application. Modlin (abstract) also teaches that peptides are reasonably interpreted to be encompassed by "bioactive agent". Therefore it would have been obvious to one of ordinary skill to make and use a bioactive agent.

Claims 19, 21, 33-36, 39-42, 63, 65, 77-80, 83-86, 113, 115-118, 121, 122-125, 132 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45-49 of U.S. Patent No. 6,017,544 issued 01/25/2000 (09/061365 filed 04/16/1998).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the active ingredient in the immunogenic population of the instant case in independent claims 19, 21, 63, and 65, a composition comprising a population of purified human stress protein-peptide complexes obtained from human tumor, more specifically a human gp96 noncovalently associated with a peptide, further comprising a cytokine (GM-CSF) in dependent claims 113, 121, 132 is also recited in claims 45-49 of U.S. Patent No. 6,017,544.

However, claims 1, 6, and 11 of U.S. Patent No. 6,017,544 make it clear that the gp96-peptide complex is "immunogenic" *in vivo*, and not any other agent. Therefore, the preamble "immunogenic population" in the instant application is an intended use. In other words, there is no difference in the composition of both "immunogenic population" of the instant claims and "composition" in U.S. Patent No. 6,017,544. The difference is semantics.

Claims 57, 58, 101, 102, 113, 114 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45-49 of U.S. Patent No. 6,017,544 in view of Roitt et al. (Immunology, 3rd ed. Mosby, London, England, 1993).

The instant claims are drawn to an immunogenic population of the respective base claims plus adjuvants.

The claims of U.S. Patent No. 6,017,544 do not recite adjuvant. However, Roitt et al. (page 15.10) teach that adjuvants evoke stronger immune responses if they are mixed with bacterial components, such as an antigen, before the effective filing date of the application. Therefore, it would have been obvious to one of ordinary skill to make and use an immunogenic population of human gp96 protein-peptide complexes further comprising an adjuvant with a reasonable expectation of success.

Claims 111, 119 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45-49 of U.S. Patent No. 6,017,544 in view of Nakatsuwaga (U.S. Patent No. 4,434,788 issued 3/04/1984) and further in view of Sela et al. (U.S. Patent No. 4,093,607 issued 6/06/1978).

The instant claims are drawn to an immunogenic population of the respective base claims plus a chemotherapeutic agent or an antibiotic.

The claims of U.S. Patent No. 6,017,544 do not recite chemotherapeutic agent or an antibiotic. However, Nakatsuwaga (column 12, claim 12) teaches that an anti-tumor agent include anti-metabolites, anti-tumor antibiotics, and alkylating agents which encompass chemotherapeutic and antibiotic compositions for cancer treatment before the effective filing date of the application. Sela et al. (column 1, lines 1-48) teach immunologic chemotherapeutic agents and anti-tumor antibiotics comprising antigen binding dimers covalently bound to drugs before the effective filing date of the application. Therefore it would have been obvious to one of ordinary skill to make and use a chemotherapeutic or antibiotic agent.

Claims 112, 120 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45-49 of U.S. Patent No. 6,017,544 in view of Kashdan (U.S. Patent No. 4,795,641 issued 01/03/1989) and further in view of Modlin (Surgery, Gynecology and Obstetrics, 1979, 149(5): 751-69).

The instant claims are drawn to an immunogenic population of the respective base claims plus a bioactive agent.

The claims of U.S. Patent No. 6,017,544 do not recite a bioactive agent.

The specification of the instant application does not define the boundary of "bioactive agent". Therefore, the office turned to the prior art to see what is encompassed by "bioactive agent". Kashdan (columns 15-16, claims 12-13) teaches that bioactive agents include a broad category of any type of agent that is bioactive before the effective filing date of the application. Modlin (abstract) also teaches that peptides are reasonably interpreted to be encompassed by "bioactive agent". Therefore it would have been obvious to one of ordinary skill to make and use a bioactive agent.

Claims 19, 21, 33-36, 39-42, 63, 65, 77-80, 83-86, 115-118, 122-125 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-30 of copending Application No. 10/386775 filed 03/07/2003.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the active ingredient in the "immunogenic population" of the instant case in independent claims 19, 21, 63, and 65, a "purified population of mammalian stress protein-peptide complexes" purified from mammalian tumors, more specifically a gp96 noncovalently associated with a peptide, is also recited in claims 28-30 of copending Application No. 10/386775.

However, claims 1, 31, 35, 39, 43, and 47 of copending Application No. 10/386775 make it clear that the gp96-peptide complex is "immunogenic" *in vivo*, and not any other agent. Therefore, the preamble "immunogenic population" in the instant application is an intended use. In other words, there is no difference in the composition of both "immunogenic population" of the instant claims and "composition" in copending Application No. 10/386775. The difference is semantics.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 111, 119 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-30 of copending Application No. 10/386775 in view of Nakatsuwaga (U.S. Patent No. 4,434,788 issued 3/04/1984) and further in view of Sela et al. (U.S. Patent No. 4,093,607 issued 6/06/1978).

The instant claims are drawn to an immunogenic population of the respective base claims plus a chemotherapeutic agent or an antibiotic.

The claims of copending Application No. 10/386775 do not recite chemotherapeutic agent or an antibiotic. However, Nakatsuwaga (column 12, claim 12) teaches that an anti-tumor agent include anti-metabolites, anti-tumor antibiotics, and alkylating agents which encompass chemotherapeutic and antibiotic compositions for cancer treatment before the effective filing date of the application. Sela et al. (column 1,

lines 1-48) teach immunologic chemotherapeutic agents and anti-tumor antibiotics comprising antigen binding dimers covalently bound to drugs before the effective filing date of the application. Therefore it would have been obvious to one of ordinary skill to make and use a chemotherapeutic or antibiotic agent.

Claims 112, 120 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-30 of copending Application No. 10/386775 in view of Kashdan (U.S. Patent No. 4,795,641 issued 01/03/1989) and further in view of Modlin (Surgery, Gynecology and Obstetrics, 1979, 149(5): 751-69).

The instant claims are drawn to an immunogenic population of the respective base claims plus a bioactive agent.

The claims of copending Application No. 10/386775 do not recite a bioactive agent.

The specification of the instant application does not define the boundary of "bioactive agent". Therefore, the office turned to the prior art to see what is encompassed by "bioactive agent". Kashdan (columns 15-16, claims 12-13) teaches that bioactive agents include a broad category of any type of agent that is bioactive before the effective filing date of the application. Modlin (abstract) also teaches that peptides are reasonably interpreted to be encompassed by "bioactive agent". Therefore it would have been obvious to one of ordinary skill to make and use a bioactive agent.

Conclusion

Claims 19, 21, 33-36, 39-42, 57, 58, 63, 65, 77-80, 83-86, 101, 102, 111-125, 132 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Judy Lille Tidwell, PhD whose telephone number is 571-272-5952. The examiner can normally be reached on 8:00AM - 5:00PM, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JLT
Art Unit 1642

MISOOK YU
PRIMARY EXAMINER